GAD protein or a fragment therefore, which, when administered to the patient, prevents or inhibits the development of insulin dependent diabetes.

63. The method of claim 62, wherein the GAD protein or fragment thereof is a recombinant protein.

REMARKS

Support for "parenteral" in claim 35 is provided at e.g., p. 21, lines 1-7. Support for new claims 63 and 63 is provided at e.g., original claim 31, p. 7, line 19, p. 14, lines 12-14, and p. 12, lines 25-29. The Examiner's comments are now addressed using the paragraph numbering of the office action.

8. The Examiner's quotation of a remark attributed to the undersigned is an oversimplification of what was said in the interview and in previous responses. The relationship between GAD65, GAD67 and the 64 kDa autoantigen is correctly described in the response filed July 22, 1999 at p. 5, second paragraph with citations to supporting scientific literature. To recap briefly, there are two known forms of GAD, conventionally referred to as lower molecular weight GAD (GAD65) and higher molecular weight GAD (GAD67). Of these two forms, it is the lower molecular weight form, GAD65, that is present in the pancreatic 64 kDa autoantigen. The difference between the numerical suffixes (i.e., 64 vs. 65) does not indicate that the GAD in the 64 kDa antigen is different from GAD65 but rather is the due to historical accident in that the original measurements of molecular weight were made in different laboratories. It is well known that the apparent molecular weight of proteins can vary slightly depending on the exact conditions of measurement.

9. The Examiner says that she will not comment on the validity of issued patents. However, there is a distinction between formally declaring a patent invalid (which applicants agree the Examiner cannot do), and adapting a position in the present case that inherently casts doubt on the validity of the Florida patents. It is applicants' position that the comments in the present and previous office actions regarding the alleged lack of enablement of the present claims do inherently cast doubt on the Florida patents. This is because the present case contains at least some claims that are patentably indistinguishable from the claims in the Florida patents, the two families of filings have similar disclosure and were filed at about the same time, and the Examiner's basis for the lack of enablement rejection, if correct, would